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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/375,169 08/16/99 AITA

C 26767-1000

EXAMINER

IM22/0926

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MCNEIL, J

ART UNIT

PAPER NUMBER

1775

12


DATE MAILED:

09/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No. <b>09/375,169</b>	Applicant(s) <b>Alta et al</b>	
Examiner <b>Jennifer McNeil</b>	Art Unit <b>1775</b>	

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jun 29, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Specification*

1. The disclosure is objected to because of the following informalities: Page 1, line 9 states "...cardiovascular account for a major portion of such deaths...". Cardiovascular what?

Appropriate correction is required.

### *Claim Objections*

2. Claim 15 is objected to because of the following informalities: Claim 15, lines 1-2 read, "wherein the each of the". Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 6 depends from claim 5 which states that the outer layer is alumina, zirconia, or hafnia. It is unclear how this layer would then be of AlN, ZrN, or HfN. Does applicant intend to

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state that the material is a nitride of alumina? Or should it be a nitride of aluminum? Should claim 5 state "the group consisting of aluminum, zirconium, or hafnium compounds and be dependent from claim 1 instead of claim 5?

Claim 15 recites the limitation "the hardness-imparting and the toughness-imparting modules". There is insufficient antecedent basis for this limitation in the claim.

Claims 9 and 10 refer to a bilayer of zirconia and alumina. It is unclear as to whether the zirconia and alumina are in the same layer and the bilayer is multiple layers of this dual compositional layer or if the bilayer is alternating alumina and zirconia. Claims 17, 18, 21, and 27 also refer to bilayers in which it is unclear as to the compositions being in the same layers and repeated or if the compositions alternate in layers. From the specification and drawings it seems that the bilayers are alternating compositions of alumina, zirconia, and titania. Please clarify.

Claims 2, 9 and 10 refer to a bilayer but does not allude to the placement of this bilayer with respect to the other layers already present. Is one of the other layers present as the bilayer, or is it an additional component of the coating?

*Claim Rejections - 35 USC § 102*

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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7. Claims 1-6, 11, 12, 28, and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Schulz et al (US 5,246,787). Schulz et al teach an instrument with a wear resistant hard coating for working or processing organic materials and is also suitable as implants for the human body including a basic steel body, a transition layer, a separating layer, and a hard coating layer. The hard coating layer may be TiN, or compounds of nitrogen with zirconium or hafnium or mixtures thereof. The separating layer is aluminum oxide or may be an oxide of titanium, zirconium, or hafnium or mixtures thereof. The transition layer gradually changes from aluminum at the surface of the body to aluminum oxide at the surface of the intermediate layer. The separating and transition layers provide a plurality of ceramic bilayers between the body and the hard coating (see column 1, lines 52-60; column 2, lines 53-68; column 3, lines 1-3; column 4, lines 57-60; column 5, lines 31-38; column 6, lines 1-68, column 7, lines 1-2).

8. Claims 1-5, 7-20, 28, 29, and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Aita (US 5,472,795). Aita teaches a multilayer nanolaminate containing polycrystalline zirconia. The substrate or support (11) may be of any desired material including glass or plastic. Thin layers of zirconia are alternated with layers of alumina. Two or more layers are preferably alternately coated onto the support. Other ceramics may be used such as nitrides and carbides (col. 2, lines 61-67; col. 3, lines 1-24).

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*Claim Rejections - 35 USC § 103*

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 7, 8, and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulz et al (5,246,787) in view of Armini et al (US 5,674,293). Schulz et al teach a wear resistant hard coating for instruments used in organic settings as mentioned above where the hard coating has a thickness of 3 microns and the separating layers has a thickness of 0.5-5 microns. Schulz et al do not teach additional thicknesses which may be used. Armini et al teach coated orthopaedic implant components having a hard coating of zirconium oxide (zirconia) applied to a metallic substrate where there are multiple layers of the zirconia applied. The thickness of the coating is 5-5000 Angstroms thick and provides improved wear characteristics. (see column 2, lines 16-19, 54-67; column 3, line 1; column 7, lines 49-55). It would have been obvious to one of ordinary skill in the art at the time of the invention to apply the coatings of Schulz et al with a thickness taught by Armini et al to provide a coating with adequate thicknesses for wear resistance while conserving deposition amounts.

11. Claims 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulz et al (US 5,246,787) in view of Davidas (US 4,326,305). Schulz et al teach a wear resistant hard coating for instruments used in organic settings as mentioned above but does not include

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aluminum nitride as a choice for the hard coating. Davidas teaches artifacts usable in-vivo having a metal substrate with a coating of AlN having a thickness of 100 angstroms to 0.5 microns. The AlN coating is insulating and prevents oxidation and corrosion of the metal substrate (see column 1, lines 56-63; column 2, lines 52-62). It would have been obvious to one of ordinary skill in the art at the time of the invention to use a protective coating of AlN as taught by Davidas in place of the TiN coating of Schulz et al to provide a coating which serves to insulate the substrate and prevents oxidation and corrosion.

*Allowable Subject Matter*

12. Claims 21-27 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, set forth in this Office action.

13. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not teach or render obvious an intracorporeal implant comprising a substrate having a protective coating thereon, the protective coating comprising a plurality of modules; a first module comprising a number of bilayers comprising alternating layers of zirconia and alumina wherein the number of bilayers is greater than 1; a second module disposed on the first module comprising a number of bilayers comprising alternating layers of zirconia and titania wherein the number of bilayers is greater than 1; and a third module disposed on the second module and comprises a compound capable of forming a hydrate or hydroxide compound upon contact with an oxygen containing environment.

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*Response to Arguments*

14. Applicant's arguments filed June 29, 2001 have been fully considered but they are not persuasive. The repeated objections to the claims and specification (see above), were not addressed by applicant and are still pending.

Applicant argues that a bilayer is defined as a "film or membrane with two molecular layers". It is still not clear whether or not the bilayer contains both zirconia and alumina in separate layers or if the bilayer is alternating layers of these compounds. The definition of a bilayer does not specify that the two layers must be of different compounds. Is this a bilayer comprising two molecular layers of different material, the material chosen from the group consisting of zirconia, titania, and alumina?

Applicant argues that Schulz et al does not teach an outer layer of water-swellaable ceramic material. The outer material taught by Schulz et al may be an oxide and/or nitride of zirconium or hafnium. Applicant defines these compounds as being water-swellaable and therefore are considered to be so (see the instant specification, page 3, lines 10-17).

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer McNeil whose telephone number is (703) 305-0553. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.





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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Jones, can be reached at (703) 308-3822.

When filing a fax in Group 1700, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing of your papers. The fax number for this Group are (703) 305-3599 for "Official" faxes and (703) 3055436 for "Unofficial" faxes.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.

  
Jennifer McNeil  
Patent Examiner  
AU 1775

  
DEBORAH JONES  
SUPERVISORY PATENT EXAMINER